DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 22, 2012 and August 25, 2011 has been entered.

Amendment Entry

2. The amendment filed February 22, 2012 and August 25, 2011 has been entered. Claim 116 is new. Claims 1-60, 64, 67-76, 78, 82-85, 87-90, 92, and 102-103 are cancelled. Claims 61-63, 65-66, 77, 79-81, 86, 91, 93-101, and 104-116 are pending. Claim 61 has been amended. Claims 96-100 are withdrawn. Claims 61-63, 65-66, 77, 79-81, 86, 91, 93-95, 101, and 104-116 are under examination.

Response to Arguments

3. Applicant's arguments with respect to claims 61-63, 65-66, 77, 79-81, 86, 91, 93-101, and 104-115 have been considered but are moot in view of the rejections below.

Information Disclosure Statement

4. The information disclosure statement filed on 8/25/2011 has been considered. An initialed copy is enclosed.

Rejections Withdrawn

3. In view of the Applicant's amendment and remark following rejections are withdrawn.

a) The rejection of claims 61-63, 65-66, 79-81, 86-87, 91, 94, 101, and 114-115 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of applicants amendment thereto.

b) The rejections of claims 77, 79-81, 86-87, 91, 93-95, and 104-113 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of applicants amendment thereto.

c) The rejection of claims 61-63, 65-66, 79-81, 86-87, 91, 94, and 101, and 114-115 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in light of applicants amendment thereto.

d) The rejection of claims 77, 79-81, 86-87, and 93 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 40-43, 47-68 and 72 of copending Application No. 10/323,926 is withdrawn in light of the abandonment of the said copending application.

Claim Rejections Maintained

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. The rejection of claims 61, 77, 79, 93 and 95 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 9-12, and

14-19 of U.S. Patent No. 6,610,293 are maintained for the reasons set forth in the previous office action.

Applicants states in Applicants Arguments/Remarks on 7/17/09, will consider filing a terminal disclaimer over the 6,610,293.

5. The rejection of claims 61, 101 and 104-116 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 9-12, and 14-19 of U.S. Patent No. 6,610,293 are maintained for the reasons set forth in the previous office action.

Applicants states in Applicants Arguments/Remarks on 7/17/09, will consider filing a terminal disclaimer over the 6,610,293.

6. The rejection of claims 77, 79-81, 86-87, 93, 101, and 104-116 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 20-21, 23, 27, 47, 49, 51-54, 56, 76, and 78 of U.S. Patent No. 7,511,122 are maintained for the reasons set forth in the previous office action.

Applicants did not address this rejection in Applicants Arguments/Remarks on February 22, 2012 and August 25, 2011.

As outlined previously, claims 77, 79-81, 86-87, 93, 101, and 104-116 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 20-21, 23, 27, 47, 49, 51-54, 56, 76, and 78 of U.S. Patent No. 7,511,122.

Claims 1, 20-21, 23, 27, 47, 49, 51-54, 56, 76, and 78 of U.S. Patent No. 7,511,122 teach a composition comprising an amount of an isolated monoclonal antibody (humanized/chimeric antibody) which specifically binds to poly-glycerol phosphate of LTA of Gram positive bacteria, or antigen binding fragment thereof, and a pharmaceutically acceptable carrier, wherein the monoclonal antibody comprises the heavy/light chain variable region set forth as SEQ ID NO.87 and SEQ ID NO. 89. Furthermore , U.S. Patent No. 7,511,122 teach a composition comprising an amount of an isolated monoclonal antibody (humanized/chimeric antibody) which specifically binds to poly-glycerol phosphate of LTA of Gram positive bacteria, or antigen binding fragment thereof, and a pharmaceutically acceptable carrier, wherein the monoclonal antibody

comprises a heavy/light chain comprising the heavy/light chain complementarity determining regions (CDRs) of the monoclonal antibody 96-110 and a variable region having 80% amino acid identity with SEQ ID NO:87 and SEQ ID NO:89 and having at least 70% amino acid identity with the monoclonal antibody 96-110 heavy/light chain variable region set forth as SEQ ID NO: 87 and SEQ ID NO: 89.

Although the conflicting claims are not identical, they are not patentably distinct. The U.S. Patent No. 7,511,122 recites the "humanized/chimeric antibody". The species of the humanized/chimeric antibody anticipate the genus claims of any monoclonal antibody.

Thus, claims 77, 79-81, 86-87, 93, 101, and 104-116 encompassing the monoclonal antibody in the present application are obvious over claims 1, 20-21, 23, 27, 47, 49, 51-54, 56, 76, and 78 of U.S. Patent No. 7,511,122.

New Matter Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 61-63, 65-66, 79-81, 91 and 116 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a new matter rejection.

The claim recites the phrase "monoclonal antibody, wherein the antibody binds to the same epitope to which MAB 96-110 antibody binds". Applicant did not file an explanation in the Applicants Arguments/Remarks on August 25, 2011 stating support for the recitation set forth supra, there is no support provided in the in the written description of the specification. Therefore, it is apparent, that Applicants were not in possession of the claimed monoclonal antibody, wherein the antibody binds to the same epitope to

which MAB 96-110 antibody binds at the time of filing. Applicants pointing to the specification by page and line number where specific written description for the recititation set forth supra may resolve this issue. This is a new matter rejection.

8. Claims 61-63, 65-66, 79-81, 91 and 116 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is apparent that the isolated monoclonal antibody as claimed is required to practice the claimed invention. Specifically, it is noted that claims 61-63, 65-66, 79-81, 91 and 116 recites the deposited material. Although the ATCC Accession No. is stated in the claims the claimed invention does not provide sufficient enablement for the claimed "isolated monoclonal antibody" as recited in claims aforementioned above because an affidavit or declaration has not been filed. The deposit of biological organisms is considered by the Examiner to be necessary for the enablement of the current invention (see 37 CRF 1.808(a)). Therefore said deposits are not in full compliance with 37 CFR 1.803-1.809.

If the deposit is made under terms of the Budapest Treaty, then an affidavit or declaration by Applicants or person(s) associated with the patent owner (assignee) who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty *and* that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808. In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit, or declaration by Applicants or person(s) associated with the patent owner (assignee) who

is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the following criteria have been met:

1) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

2) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent; and

3) the deposits will be maintained for a term of at least thirty (30) years from the date of the deposit or for the enforceable life of the patent or for a period of at least five (5) years after the most recent request for the furnishing of a sample of the deposited material, whichever is longest; and

4) a viability statement in accordance with the provisions of 37 CFR 1.807; and

5) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 CRF 1.809(d) should be added to the specification. See 37 CFR 1.803 - 1.809 for additional explanation of these requirements.

Conclusion

9. No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nina A Archie
Examiner
GAU 1645
REM 3B31

/Gary B. Nickol /
Supervisory Patent Examiner, Art Unit 1645